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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,685	06/29/2001	Rene Bruno	P23,565-A US	8546

7590 08/26/2003

Alexis Barron
Synnestvedt & Lechner
2600 Aramark Tower
1101 Markter Street
Philadelphia, PA 19107-2950

EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,685	BRUNO, RENE	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *6-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

if approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-30 are pending.

Claims 6-29 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-5, and 30 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1-5, and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bruno *et al.* (Cancer Surveys, Vol. 17, pages 305-313, 1993) and Urien *et al.* (Invest. New Drugs, Vol.14, pages 147-151, 1996, IDS) for the reasons of record in Paper No. 9, pages 4-6.

Applicants argue (Paper No. 10, page 2) that the combined disclosures of the above references do not teach nor suggest any method for determining the dosage of a taxoid to administer to a patient being treated for cancer. Applicants further argue that the Examiner has failed to support the claimed method other than by restating the teachings of the above references. This argument has been considered but is not found persuasive. On the contrary, the rationale for deriving the dosage of a taxoid, based on the combination of the references, is discussed in the rejection on page 5, last paragraph. It is noted that applicants have not argued

against or addressed this rationale but have only argued that the references themselves fail to hint that the level of AAG is a factor in determining the effectiveness of taxoid in the treatment of cancer. In so doing, Applicants have argued and discussed the references individually without clearly addressing the combined teachings. For example, Applicants have quoted the last sentence of the Urien *et al.* reference which relates to the influence of AAG on the free serum fraction of docetaxel wherein it was unclear whether the free drug concentration was actually changed. However, applicants have not clearly established how this constitutes any alleged teaching away from the broader disclosure that a) AAG is the main determinant of interindividual serum binding variability of docetaxel and b) AAG is a determinant of docetaxel clearance. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981).

Clearly, to one of ordinary skill in the field of pharmacology, AAG has a direct effect on docetaxel in vivo wherein Urien *et al.* states (page 150, 2nd column) that in a recent report on population pharmacokinetics of docetaxel including 577 patients, the higher the AAG concentration, the lower the free plasma fraction and the clearance. Applicants further argue (Paper No. 10, page 3) that even if one of ordinary skill in the art had arrived at applicant's claimed method, they would not have had reasonable expectation of success. This argument has been considered but is not found persuasive because a) it was well known in the art at the time

the invention was made that docetaxel had significant therapeutic activity against a variety of malignancies (Urien *et al.*, page 147, 1st paragraph) and b) AAG directly effects the pharmocokinetics of docetaxel. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 25, 2003